

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA, *et al.*,
ex rel. JOSEPH NOCIE,

Plaintiffs,

V.

STEWARD HEALTH CARE SYSTEM, LLC,
STEWARD MEDICAL GROUP, INC., and
STEWARD ST. ELIZABETH'S MEDICAL
CENTER OF BOSTON, INC.,

Defendants.

No. 18-cv-11160-WGY

JURY TRIAL DEMANDED

UNITED STATES' COMPLAINT-IN-INTERVENTION

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Introduction

1. The United States of America (“United States”) brings this Complaint-in-Intervention against Steward Health Care System, LLC (“Steward”); Steward Medical Group, Inc. (“SMG”)¹; and Steward St. Elizabeth’s Medical Center of Boston, Inc. (“SEMC”)² (collectively, the “defendants”), to recover treble damages, restitution, and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729–33 (“FCA”). In the alternative, the United States seeks to recover damages under the common law theories of unjust enrichment and payment by mistake.

2. The Physician Self-Referral Law, 42 U.S.C. § 1395nn (commonly referred to as the “Stark Law”) prohibits, among other things, a hospital from billing Medicare for services referred by a physician with whom the hospital has a direct or indirect compensation relationship that does not meet any statutory or regulatory exception. Congress enacted the Stark Law to protect Medicare patients from physicians’ financial arrangements impacting their medical decision-making, and to protect the Medicare program from physicians’ financial relationships leading to unnecessary overutilization of services or increased costs.

3. Steward is a for-profit company that wholly owns SMG and SEMC, which are part of Steward’s integrated and sophisticated healthcare network. The defendants were well aware of the Stark Law and its importance to the Medicare program. The defendants had policies and trainings for their employees concerning the significance of and compliance with the

¹ The relator’s complaint named Steward Medical Group. The exact name of the business entity is Steward Medical Group, Inc.

² The relator’s complaint named St. Elizabeth’s Medical Center. The exact name of the business entity is Steward St. Elizabeth’s Medical Center of Boston, Inc.

Stark Law. Further, SEMC repeatedly certified on its Medicare enrollment forms and annual cost reports that it complied with the Stark Law.

4. The defendants nevertheless entered into multiple, successive compensation arrangements with Dr. Arvind Agnihotri (“Dr. Agnihotri”), a cardiac surgeon, that plainly violated the Stark Law. The defendants entered into these arrangements in order to increase the number of cardiovascular surgeries at SEMC in Boston, and to increase SEMC’s revenue via reimbursement from Medicare and other insurers. Under these arrangements, SMG employed Dr. Agnihotri, and SEMC had an indirect compensation arrangement with Dr. Agnihotri. SEMC submitted claims for payment to Medicare for designated health services that SEMC furnished pursuant to Dr. Agnihotri’s prohibited referrals, in violation of the Stark Law.

5. An indirect compensation arrangement between a hospital and a referring physician can be permissible under an exception to the Stark Law, if the arrangement meets *both* of the following requirements: (1) the compensation the physician receives must be fair market value, *and* (2) the compensation the physician receives must not be determined in any manner that takes into account the volume or value of referrals by the physician to the hospital.

6. Dr. Agnihotri’s indirect compensation arrangement with SEMC unequivocally failed both requirements. Specifically, from January 1, 2013 through March 31, 2022 (the “Relevant Period”), SMG paid Dr. Agnihotri aggregate annual compensation that was in excess of fair market value (“FMV”). During that same period, SMG paid Dr. Agnihotri approximately \$4.8 million in incentive compensation that the defendants determined in a manner that varied with, and took into account, the volume or value of Dr. Agnihotri’s referrals to SEMC or other business he generated for SEMC.

7. Any claim submitted to Medicare in violation of the Stark Law is false within the meaning of the FCA. Thus, any claims that SEMC submitted to Medicare for designated health services that Dr. Agnihotri referred to SEMC, during the period when their indirect compensation arrangement failed to satisfy the requirements of an applicable exception to the Stark Law, are false under the FCA.

8. The defendants knowingly submitted, or caused the submission, of at least 1,000 false claims to Medicare. The SMG Presidents, acting on behalf of SMG, entered into the compensation arrangements with Dr. Agnihotri despite hearing repeated concerns from SEMC's President and CEO that Dr. Agnihotri's incentive compensation arrangement was improper. Further, the SMG Presidents, on behalf of SMG, agreed to the compensation arrangements with Dr. Agnihotri despite receiving Steward's annual training on the Stark Law. In agreeing to their compensation arrangements with Dr. Agnihotri, the defendants failed to follow Steward's own detailed policies and procedures for structuring and approving compensation arrangements with physicians. Notwithstanding all the above, for the duration of the Relevant Period, the defendants kept the same basic, and improper, structure in place for determining Dr. Agnihotri's incentive compensation.

9. The United States estimates that, because of the defendants' fraudulent conduct in violation of the FCA, Medicare paid tens of millions of dollars in false claims, which the United States now seeks to recover, in addition to FCA damages and penalties, all in amounts to be determined at trial.

10. The claims against the defendants relate back to the original filing date of the relator's Complaint pursuant to 31 U.S.C. § 3731(c).

Jurisdiction and Venue

11. This Court has subject matter jurisdiction over the FCA claims pursuant to 31 U.S.C. §§ 3730(a) and 3732(a) and 28 U.S.C. §§ 1331 and 1345, and over the common law claims pursuant to 28 U.S.C. §§ 1367(a) and 1345.

12. The Court has jurisdiction to entertain a qui tam action pursuant to 31 U.S.C. § 3730(b).

13. This Court may exercise personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a), as all the defendants transact business in this District.

14. Venue lies in this District for the FCA claims pursuant to 31 U.S.C. § 3732(a), and for the common law claims pursuant to 28 U.S.C. § 1391(b) and (c), because all the defendants transact business in this District. SMG employs physicians to work in Massachusetts, SEMC is in Massachusetts, and Steward transacts business in Massachusetts.

Parties

The United States

15. Plaintiff the United States is acting on behalf of the United States Department of Health and Human Services (“HHS”) and the Centers for Medicare & Medicaid Services (“CMS”), which administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* (“Medicare”).

The Relator

16. Relator Joseph Nocie was the Chief Financial Officer (“CFO”) of SEMC from approximately May 2016 to November 2017. He was employed by Steward and worked for SEMC in Massachusetts. He currently resides in California.

Steward

17. Steward is one of the largest, private, for-profit health care networks in the nation. Steward is a Delaware corporation with a principal place of business in Dallas, Texas. Steward has an office located in Boston, Massachusetts.

18. Steward is an integrated healthcare system. *See* <https://www.steward.org/> (last visited Dec. 6, 2023) (“Our transformative, fully *integrated model* represents a new beginning for America’s health care system and others around the world . . . Steward Health Care has perfected a unique vertically and horizontally integrated model . . .” (emphasis added)).

SMG

19. SMG is a Delaware corporation with a principal office in Dallas, Texas. SMG employs physicians that provide medical and administrative services and work in Massachusetts, including at SEMC.

SEMC

20. SEMC is a hospital in the Brighton neighborhood of Boston, Massachusetts. SEMC is a Delaware corporation with an office in Boston. SEMC provides hospital services at 736 Cambridge St., Brighton, MA 02135. Steward owns and operates SEMC. Some SMG-employed physicians, including Dr. Agnihotri, work at SEMC. SEMC receives all funds reimbursed from federal health care programs for services provided by the hospital.

The Relationship Among Steward, SMG, and SEMC

21. Steward wholly owns SEMC and SMG. Steward, SEMC, and SMG all have the same principal office at 1900 N. Pearl Street, Suite 2400, Dallas, TX 75201.

22. Steward, SEMC, and SMG share personnel. For instance, Mark Rich is the Treasurer, Herbert Holtz is the Secretary, and Nathalie Hibble is the Assistant Secretary of both SEMC and SMG. As another example, Dr. Michael Callum is a Manager of Steward and a Director of SMG, and during part of the Relevant Period he was the President and CEO of SMG.

23. To assist with operational expenses, including deficits, related to physicians employed by SMG who work solely at SEMC, Steward effectuates intercompany transfers of funds between SEMC and SMG. Through these intercompany transfers, SEMC makes subsidy payments to SMG, known as a hospital subsidy, and payments for directorships and various administrative roles to offset expenses associated with SMG's employment of physicians. The defendants calculate the hospital subsidy payment for each physician based on the expenses associated with employing that physician less the revenue that SMG expects the physician to generate for SMG.

Legal Background

I. THE FALSE CLAIMS ACT AND THE STARK LAW

24. The FCA establishes liability to the United States for any individual who, or entity that, “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1)(A), or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” 31 U.S.C. § 3729(a)(1)(B), or “conspires to commit a violation” of the above, 31 U.S.C. § 3729(a)(1)(C). The FCA defines “knowingly” to include actual knowledge, reckless disregard, or deliberate ignorance of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

25. Claims for reimbursement submitted to Medicare in violation of the Stark Law (as described below) are ineligible for payment and are materially false claims actionable under the FCA.

26. Enacted as amendments to the Social Security Act, the Stark Law prohibits a physician from referring “designated health services,” as defined in 42 U.S.C. § 1395nn(h)(6) and 42 C.F.R. § 411.351, to hospitals and other entities with which the physician has a “financial relationship” (as defined in the statute and regulations) that does not satisfy the requirements of an applicable exception. The Stark Law also prohibits the hospital or other entity from submitting claims to Medicare for designated health services furnished pursuant to a prohibited referral and prohibits Medicare payment for such claims.

27. “Designated health services” include inpatient and outpatient hospital services. *See* 42 U.S.C. § 1395nn(h)(6).

28. “Financial relationships” include “compensation arrangements” involving the payment of remuneration and may be direct or indirect, as defined in 42 U.S.C. § 1395nn(h)(1)(A) and (h)(1)(B), and 42 C.F.R. § 411.354(c).

29. The Stark Law provides that, unless an exception under 42 U.S.C. § 1395nn applies and its requirements are satisfied, if a physician “has a financial relationship with an entity ... then (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made” by Medicare and “(B) the entity may not present or cause to be presented a claim ... or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).” 42 U.S.C. § 1395nn(a)(1).

30. The Stark Law is a strict liability statute.

31. The Stark Law explicitly states that Medicare may not pay for any designated health services referred in violation of the statute. *See* 42 U.S.C. § 1395nn(g)(1).

32. In addition, the regulations interpreting the Stark Law expressly require that any entity collecting payment for designated health services “performed pursuant to a prohibited referral must refund all collected amounts on a timely basis.” 42 C.F.R. § 411.353(d).

33. During most of the Relevant Period, for purposes of the Stark Law, an indirect compensation arrangement existed if: (1) there was an unbroken chain of financial relationships between the referring physician and the entity furnishing designated health services (“DHS entity”)³; (2) the referring physician received aggregate compensation from the person or entity in the chain with which the physician had a direct financial relationship that varied with, or took into account, the volume or value of the physician’s referrals to the DHS entity or other business generated⁴ by the referring physician for the DHS entity⁵; and (3) the DHS entity had knowledge that the referring physician received aggregate compensation that varied with, or took into account, the volume or value of referrals or other business generated by the referring physician

³ Hospitals, such as SEMC, are DHS entities. *See* 42 U.S.C. § 1395nn(h)(6) and 42 C.F.R. § 411.354(c)(2) (2020).

⁴ “Other business generated” includes services paid by other federal payors, and private or commercial payors. *See* 66 Fed. Reg. 856, 877 (Jan. 4, 2021) and 85 Fed. Reg. 77492, 77547 (Dec. 2, 2020).

⁵ Beginning in January 2021, CMS removed “took into account” from this requirement. *See* 42 C.F.R. § 411.354(c)(2) (2021).

for the DHS entity.⁶ 42 C.F.R. § 411.354(c)(2) (2020). These requirements were in effect during most of the Relevant Period, including January 1, 2013 to late January 2021.⁷

34. Generally, under the Stark Law, if a physician has an indirect compensation arrangement with a hospital, then the physician may not refer designated health services to the hospital, and the hospital may not submit claims to Medicare for designated health services referred by that physician. There is an exception, however, for certain indirect compensation arrangements. *See* 42 C.F.R. § 411.357(p).

35. To meet that regulatory exception, the indirect compensation arrangement between a hospital and a physician must satisfy both of these requirements: (1) the compensation the physician receives must be fair market value, and (2) the compensation the physician receives must not be determined in any matter that takes into account the volume or value of referrals by the physician to the hospital. *See* 42 C.F.R. § 411.357(p)(1)(i).

36. Under the Stark Law, a hospital cannot submit claims to Medicare for designated health services referred by a physician with which it has an indirect compensation arrangement

⁶ Beginning in January 2021, CMS removed “took into account” from this requirement. *See* 42 C.F.R. § 411.354(c)(2) (2021).

⁷ Beginning in January 2021, CMS added regulatory language concerning the amount of compensation that the physician receives per individual unit. *See* 42 C.F.R. § 411.354(c)(2) (2021). Under the revised requirements for determining if an indirect compensation arrangement exists, there is an indirect compensation arrangement if, in addition to the other requirements, the compensation that the physician receives per individual unit is (1) not fair market value for items or services actually provided, and (2) could increase as the number of the physician’s referrals increase, or decrease as the number of the physician’s referrals decrease. *Id.* When a physician is not compensated solely per item provided or solely per service provided, then the “individual unit” analyzed is time. *See id.* When measured by time the individual unit is typically a year. Effective January 1, 2022, CMS clarified this provision—without substantive change in its meaning. *See* 42 C.F.R. § 411.354(c)(2) (2022).

that does not satisfy the exception for indirect compensation arrangements (or any other applicable exception). Any claim submitted to Medicare in violation of the Stark Law is false within the meaning of the FCA.

II. MEDICARE

37. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act through Title XVIII of the Social Security Act. 42 U.S.C. §§ 1395 *et seq.* (“Medicare”). HHS is responsible for administering and supervising the Medicare program, which it does through CMS.

38. A person’s age, disability, or affliction with end-stage renal disease determines their entitlement to Medicare benefits. *See* 42 U.S.C. §§ 426, 426-1.

39. Individuals who are insured under Medicare are referred to as Medicare “beneficiaries.”

40. The Medicare regulations define a “provider” to include “a hospital . . . that has in effect an agreement to participate in Medicare.” 42 C.F.R. § 400.202. There are four parts to the Medicare Program: Part A authorizes payment for institutional care, including inpatient hospital care, skilled nursing facility care, and home health care (*see* 42 U.S.C. §§ 1395c–1395i-4); Part B primarily covers outpatient care, including physician services and ancillary services (*see* 42 U.S.C. § 1395k); Part C is the Medicare Advantage Program, which provides Medicare benefits to certain Medicare beneficiaries through private health insurers (*see* 42 U.S.C. § 1395w-21 *et seq.*); and Part D provides prescription drug coverage (*see* 42 U.S.C. § 1395w-101 *et seq.*; 42 C.F.R. § 423.1 *et seq.*).

41. Under the Medicare program, CMS makes payments for hospital inpatient and outpatient services on a per-claim basis, and through the year-end cost-report reconciliation process described below.

42. CMS makes payments through Medicare Administrative Contractors (“MACs”). CMS relies on MACs to serve as the “primary operational contact” with health care providers enrolled in Medicare. <https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac> (last visited Dec. 15, 2023). MACs administer Medicare Part A and Medicare Part B claims, including processing claims, making for payments to providers on behalf of Medicare, and enrolling providers among other administrative responsibilities. *Id.*

43. Upon discharge of Medicare beneficiaries from a hospital, the hospital submits Medicare Part A claims for reimbursement for inpatient services delivered to those beneficiaries. 42 C.F.R. §§ 413.1, 413.60, 413.64. Hospitals submit claims to Medicare Part A electronically using a standard machine-readable format, which is known as the 837I format. The claim form instructions, found in Chapter 25, section 75 of the Medicare Claims Processing Manual, set forth the Medicare requirements for use of the various codes in completing the form.

44. When a physician furnishes professional patient care services in a hospital setting to a patient the physician referred to the hospital, they (or an entity to which they have assigned billing rights) may bill Medicare for their “professional” services, which include performing procedures and interpreting test results, using a CMS Form 1500. The hospital may submit a separate claim to Medicare for the “technical” or “facility” component of the services furnished, as described in the preceding paragraph, under which the hospital is reimbursed for furnishing,

among other things, equipment and non-physician staff. In these circumstances, the hospital's facility fee is the result of the physician's referral.

45. Providers must be enrolled in Medicare in order to be reimbursed by the Medicare program. *See* 42 C.F.R. § 424.505. To enroll in Medicare, institutional providers such as hospitals periodically must complete a Medicare Enrollment Application (often called a Form CMS-855A). In completing the Medicare Enrollment Application, an institutional provider certifies:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. ***I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law),*** and on the provider's compliance with all applicable conditions of participation in Medicare.

CMS-855A (07/11) (emphasis added). Exhibit 1 contains the pertinent pages from one of SEMC's 855A certifications.

46. The Medicare Enrollment Application also summarizes the FCA in a separate section that explains the penalties for falsifying information in the application to "gain or maintain enrollment in the Medicare program." *Id.*

47. Medicare enrollment regulations further require providers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

48. As a prerequisite to Medicare payment under Medicare Part A, CMS also requires hospitals to annually submit a Form CMS-2552 (commonly known as a "cost report"). A cost

report is the final claim that a provider submits to a MAC for items and services furnished to Medicare beneficiaries during the year covered by the report.

49. After the end of a hospital's fiscal year, the hospital files its hospital cost report with the MAC, stating the amount of Part A reimbursement the hospital believes it is due for the year, or the amount of excess reimbursement it has received during the year through interim payments that the hospital owes back to Medicare. *See* 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20; *see also* 42 C.F.R. § 405.1801(b)(1). Medicare relies upon the hospital cost report to determine whether the hospital is entitled to more reimbursement than already received or whether the provider has been overpaid and must reimburse Medicare. *See* 42 C.F.R. §§ 405.1803, 413.60, and 413.64(f)(1).

50. Medicare Part A reimbursement for hospital services, *see* 42 U.S.C. § 1395ww, is based on a prospective payment system (via Diagnosis Related Groups or "DRGs") using the claims submitted by the hospital for patient discharges (listed on Form CMS-1450) during the course of the fiscal year. On the hospital cost report, the payments for services are added to any other Medicare Part A add-on payments due to the provider. This total determines Medicare's liability for services furnished to Medicare Part A beneficiaries during the course of a fiscal year. From this sum, the interim payments made to the provider based on claims it submitted during the year are subtracted to determine the amount due to or due from the provider.

51. Every hospital cost report contains a certification that must be signed by the chief administrator of the provider or a responsible designee of the administrator.

https://www.costreportdata.com/worksheets/Form_S001.pdf (last visited Dec. 6, 2023).

52. That chief administrator or designee is required to certify, in pertinent part:

[T]o the best of my knowledge and belief, it [the hospital cost report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

Id.

53. The hospital cost report certification page also includes the following notice:

MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED BY THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WHERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

Id.

54. Thus, a provider must certify (1) that the filed hospital cost report is truthful, *i.e.*, that the cost information contained in the report is true and accurate; (2) that it is correct, *i.e.*, that the provider is entitled to reimbursement for the reported costs in accordance with applicable instructions; (3) that it is complete, *i.e.*, that the hospital cost report is based upon all information known to the provider; and (4) that the services provided in the cost report were billed in compliance with applicable laws and regulations, including the Stark Law.

55. A hospital is required to disclose all known errors and omissions in its claims for Medicare Part A reimbursement (including its cost reports) to its MAC.

56. Medicare, through its MACs, has the right to audit a provider hospital's cost reports and financial representations to ensure their accuracy and preserve the integrity of the Medicare Trust Funds. This right includes the right to make retroactive adjustments to hospital cost reports previously submitted by a provider if any overpayments have been made. *See* 42 C.F.R. § 413.64(f).

57. During the Relevant Period, National Government Services, Inc. ("NGS") was the MAC for Massachusetts.

Factual Allegations

I. THE DEFENDANTS' COMPENSATION ARRANGEMENTS WITH DR. AGNIHOTRI

58. The defendants recruited Dr. Agnihotri to work for SMG at SEMC because they wanted him to grow the Cardiac Surgery program at SEMC. In early 2012, the volume of cardiac surgery cases at SEMC was lower than the defendants wanted. Before hiring Dr. Agnihotri, surgeons performed approximately 180 to 200 cardiac surgery cases at SEMC per year. In hiring Dr. Agnihotri, the defendants wanted to increase the volume of cardiac surgeries at SEMC and prevent physicians from referring Steward patients to competitor hospitals for cardiac surgery.

59. Dr. Ralph de la Torre and Dr. Michael G. Callum recruited Dr. Agnihotri. Dr. de la Torre is the Chairman and CEO of Steward. Upon information and belief, Dr. de la Torre and Dr. Agnihotri had previously worked together and were friends before Dr. Agnihotri's recruitment. At the time of the contract negotiations for Dr. Agnihotri's original compensation arrangement with SMG, Dr. Callum was the President of SMG.

60. Dr. Callum negotiated Dr. Agnihotri's compensation arrangement and kept Dr. de la Torre informed of the status of the negotiations with Dr. Agnihotri.

61. During the contract negotiations, Dr. Callum acted as an agent of SMG, and Dr. de la Torre acted as an agent of Steward.

62. Dr. Callum, on behalf of SMG, and Dr. de la Torre, on behalf of Steward, approved the contract with Dr. Agnihotri.

63. SMG hired Dr. Agnihotri and assigned him to work at SEMC and serve as the Chief of Cardiac Surgery at SEMC. The effective date of Dr. Agnihotri's employment agreement was August 31, 2012. Dr. Agnihotri served as SEMC's Chief of Cardiac Surgery from approximately August 31, 2012 through March 31, 2022.

64. From January 1, 2018 through March 31, 2022, Dr. Agnihotri also served as Steward's System Chief of Cardiac Surgery. This was a leadership role at Steward.

65. Beginning January 1, 2013, Dr. Agnihotri was eligible to receive incentive compensation.

66. Per the compensation arrangement, SMG agreed to pay Dr. Agnihotri a \$1,000,000 sign-on bonus, base compensation (salary)⁸, the opportunity to receive incentive compensation,⁹ and

⁸ Dr. Agnihotri's base salary was comprised of (1) an annualized base clinical compensation and (2) compensation for administrative duties.

⁹ During the Relevant Period, depending on which version of Dr. Agnihotri's compensation arrangement was in effect, Dr. Agnihotri was eligible to receive up to \$600,000, \$700,000, or \$800,000 per year in incentive compensation.

for some of the years, so-called “quality” compensation.¹⁰ The chart below shows the aggregate compensation, excluding fringe benefits, by year that SMG paid to Dr. Agnihotri.

Year	Base Salary	Sign-On Bonus	Incentive Compensation ¹¹	Quality Compensation	Aggregate Compensation
2012 ¹²	\$ 219,231	\$ 200,000	N/A	N/A	\$ 419,231
2013	\$ 750,001	\$ 200,000	N/A	N/A	\$ 950,001
2014	\$ 778,847	\$ 200,000	\$ 498,000	N/A	\$ 1,476,847
2015	\$ 750,001	\$ 200,000	\$ 505,500	N/A	\$ 1,455,501
2016	\$ 750,001	\$ 200,000	\$ 620,000	N/A	\$ 1,570,001
2017	\$ 750,001	N/A	\$ 716,000	N/A	\$ 1,466,001
2018	\$ 900,000	N/A	\$ 670,000	N/A	\$ 1,570,000
2019	\$ 900,000	N/A	\$ 706,000	\$ 100,000	\$ 1,706,000
2020	\$ 900,000	N/A	\$ 548,000	\$ 100,000	\$ 1,548,000
2021	\$ 900,000	N/A	\$0	\$ 100,000	\$ 1,000,000
2022	\$ 856,800	N/A	\$ 605,000	\$ 100,000	\$ 1,561,800

67. In addition to his aggregate wages, SMG provided Dr. Agnihotri with fringe benefits (e.g., health, dental, and life insurance), reimbursement for continuing medical

¹⁰ Starting January 1, 2019, Dr. Agnihotri was “eligible to receive quality Incentive Compensation of up to \$100,000 based upon the achievement of the performance metrics by the St. Elizabeth’s Medical Center Division of Cardiac Surgery.” The performance metrics related to coronary artery bypass graft procedures (“CABG”), a type of cardiac surgery. *See* <https://www.nhlbi.nih.gov/health/coronary-artery-bypass-grafting> (Last visited Dec. 6, 2023). The performance metrics were (1) “STS Isolated CABG procedures in hospital mortality rates,” (2) “STS Isolated CABG procedures and operative mortality rates,” (3) STS Isolated CABG procedures any complications,” (4) “Total ventilation hours for Isolated CABG procedures,” and (5) “Isolated CABG procedures smoking cessation counseling.” In order to qualify for the full quality compensation, the Division needed to have a number on the first four performance metrics less than or equal to “STS ‘Like Group’ for most recently available reporting period;” and for the fifth performance metric the number needed to be greater than or equal to “STS ‘Like Group’ for most recently available reporting period.” The employment agreement does not define STS, but presumably SMG and Dr. Agnihotri intended STS to mean the data from the Society of Thoracic Surgeons Adult Cardiac Surgery Database. *See* <https://www.sts.org/sts-national-database> (Last visited Dec. 6, 2023).

education and related travel expenses, and medical malpractice insurance. Those amounts were in addition to the aggregate compensation listed in the chart.

68. From January 1, 2013 through March 31, 2022, SMG’s agreement, including any amendments, with Dr. Agnihotri provided for incentive compensation that increased as the volume of Dr. Agnihotri’s referrals to SEMC and the other business he generated for SEMC increased.

69. SMG’s original employment agreement with Dr. Agnihotri stated that Dr. Agnihotri was eligible for incentive compensation based on:

the number of surgical cardiovascular cases performed by the Division of Cardiac Surgery during each year . . . For purposes of calculating Incentive Compensation, a ‘Surgical Cardiovascular Case’ shall mean any surgical cardiac procedure performed by the Division of Cardiac Surgery *involving the use of an operating room*.

Exhibit 2 (emphasis added). As discussed below, SMG and Dr. Agnihotri later amended this provision to read “performed by the St. Elizabeth’s Medical Center Division for Cardiac Surgery.” Although the original agreement did not specifically mention SEMC in this provision, the Division of Cardiac Surgery (hereinafter “the Division”), which Dr. Agnihotri headed,¹³ exclusively used the operating rooms at SEMC.

¹¹ After the close of each calendar year, the defendants calculated Dr. Agnihotri’s incentive compensation and paid it out during the following calendar year. For example, SMG paid Dr. Agnihotri incentive compensation in 2014 based on the number of Cardiovascular Cases at SEMC in 2013.

¹² Dr. Agnihotri’s started at SEMC on or around August 31, 2012.

¹³ In 2013, the Division comprised Dr. Agnihotri and Dr. Tollis. In 2014, Dr. Agnihotri, Dr. Ketchedjian, Dr. Tam, and Dr. Tollis worked in the Division. Dr. Tollis departed during 2014.

70. Each time the Division used an operating room at SEMC for a Surgical Cardiovascular Case for a Medicare beneficiary, SEMC billed Medicare for an inpatient or outpatient hospital service.

71. The inpatient and outpatient hospital services (that is, the “facility fees”) billed by SEMC for the procedures Dr. Agnihotri performed at SEMC are the consequence of Dr. Agnihotri’s referrals to SEMC. *See United States ex rel. Drakeford v. Tuomey*, 675 F.3d 394, 406-7 (4th Cir. 2012) (finding that the facility fee for the services performed by a physician is a referral within the meaning of the Stark Law).

72. SMG and Dr. Agnihotri amended the terms pertaining to Dr. Agnihotri’s incentive compensation several times over the Relevant Period. In each version of the agreement, the Division had to perform a threshold number of Surgical Cardiovascular Cases in an operating room at SEMC for Dr. Agnihotri to be eligible to receive his incentive compensation. If, in any given year, the number of Surgical Cardiovascular Cases met or exceeded the threshold, then Dr. Agnihotri received a lump sum incentive bonus, plus an amount of money for each Surgical Cardiovascular Case above the threshold, up to a ceiling. The formula for determining Dr. Agnihotri’s compensation always took into account (i) Surgical Cardiovascular Cases Dr. Agnihotri referred to SEMC in which he personally performed the procedure, and (ii) Surgical Cardiovascular Cases referred to SEMC by other physicians in the Division and performed by the other physicians in the Division. Dr. Agnihotri only received incentive compensation for the Division’s Surgical Cardiovascular Cases at SEMC; he did not

Upon information and belief, for the remainder of the Relevant Period the Division was comprised of Drs. Agnihotri, Ketchedjian, and Tam.

receive incentive compensation for Surgical Cardiovascular Cases that did not occur at SEMC. Therefore, for the entire Relevant Period, Dr. Agnihotri's compensation was determined in a manner that varied with, and took into account, the volume or value of his referrals and the other business he generated for SEMC. Put another way, the mathematical formula for calculating Dr. Agnihotri's compensation included a variable for the volume of Dr. Agnihotri's referrals to SEMC.

73. Dr. Callum, then President of SMG, signed Dr. Agnihotri's original employment agreement on behalf of SMG on June 28, 2012. Under the original employment agreement, if the Division performed 400 Surgical Cardiovascular Cases (the threshold) during the calendar year, then Dr. Agnihotri would receive \$250,000. The agreement includes a chart showing that Dr. Agnihotri would receive \$2,000 per Surgical Cardiovascular Case for cases 401 through 500, and \$1,500 per Surgical Cardiovascular Case for cases 501 to 600. If the Division performed 600 Surgical Cardiovascular Cases, then Dr. Agnihotri would receive \$600,000 in incentive compensation. Below is a portion of the incentive compensation provision from the agreement. The full agreement is attached as Exhibit 2.

Incentive Compensation

Beginning on January 1, 2013, Physician shall be entitled to receive Incentive Compensation of up to \$600,000 per year during the Initial Term. Physician shall receive as Incentive Compensation the amount listed below which corresponds to the number of surgical cardiovascular cases performed by the Division of Cardiac Surgery during each year of the Initial Term of the Agreement. For purposes of calculating Incentive Compensation, a "Surgical Cardiovascular Case" shall mean any surgical cardiac procedure performed by the Division of Cardiac Surgery involving the use of an operating room. Surgical Cardiovascular Cases shall be measured each year from January 1 to December 31. SMG shall make payments to the Physician in the applicable amount set forth below within 90 days after the end of the applicable year.

Surgical Cardiovascular Cases	Incentive Compensation
400	\$250,000
401	\$252,000
402	\$254,000

Exhibit 2.

74. On November 1, 2013, SMG, acting through Dr. Callum, and Dr. Agnihotri executed the First Amendment to Dr. Agnihotri's employment agreement. The primary reason for the First Amendment was to increase the ceiling for the incentive compensation to continue to incentivize and reward Dr. Agnihotri for growing the Division by referring more cases to SEMC. The First Amendment increased the ceiling for Dr. Agnihotri's incentive compensation from \$600,000 to \$800,000, by adding to the chart that Dr. Agnihotri would receive \$1,500 per Surgical Cardiovascular Case for cases 601 to 800. The parties otherwise left the structure of the incentive compensation plan unchanged. Below is a portion of the incentive compensation provision from the First Amendment to Dr. Agnihotri's employment agreement. The entire First

Amendment is attached as Exhibit 3.

<u>Exhibit B</u>	
<u>Incentive Compensation</u>	
<p>Beginning on January 1, 2014, Physician shall be entitled to receive Incentive Compensation of up to \$800,000 per year during the Initial Term. Physician shall receive as Incentive Compensation the amount listed below which corresponds to the number of surgical cardiovascular cases performed by the Division of Cardiac Surgery during each year of the Initial Term of the Agreement. For purposes of calculating Incentive Compensation, a "Surgical Cardiovascular Case" shall mean any surgical cardiac procedure performed by the Division of Cardiac Surgery involving the use of an operating room. Surgical Cardiovascular Cases shall be measured each year from January 1 to December 31. SMG shall make payments to the Physician in the applicable amount set forth below within 90 days after the end of the applicable year.</p>	
Surgical Cardiovascular Cases	Incentive Compensation
400	\$250,000
401	\$252,000
402	\$254,000

Exhibit 3 (emphasis added).

75. In January 2018, Dr. Callum was directly involved with negotiating the terms of a Second Amendment concerning the incentive compensation with Dr. Agnihotri.

76. Between the execution of the First and Second amendments, Sanjay K. Shetty, M.D., replaced Dr. Callum as the president of SMG, and Dr. Callum became the Executive Vice President of Steward.

77. Prior to the execution of the Second Amendment, in November 2018, Dr. Shetty communicated with Dr. Callum regarding the structure of Dr. Agnihotri's bonus compensation.

78. SMG, acting through Dr. Shetty, and Dr. Agnihotri executed a Second Amendment, effective January 1, 2019, that increased the threshold number of cases to trigger Dr. Agnihotri's incentive compensation from 400 cases to 600 cases and changed the payment

for each Surgical Cardiovascular Case above the 600-case threshold to \$1,000 per case. The amendment made clear that the Division was the “St. Elizabeth’s Medical Center Division of Cardiac Surgery,” further evidencing the defendants’ intent to reward Dr. Agnihotri for his referrals of cases to SEMC.¹⁴ Below is a portion of the incentive compensation provision from the Second Amendment to Dr. Agnihotri’s employment agreement. The entire Second Amendment is attached as Exhibit 4.

<u>EXHIBIT B</u>	
Commencing on January 1, 2019, Physician shall be entitled to receive Incentive Compensation of up to \$800,000 per year during the term of the Agreement. Physician shall receive as Incentive Compensation the amount listed below which corresponds to the number of surgical cardiovascular cases performed by the St. Elizabeth’s Medical Center Division of Cardiac Surgery during each year during the term of this Agreement. For purposes of calculating Incentive Compensation, a “Surgical Cardiovascular Case” shall mean any surgical cardiac procedure performed by the Division of Cardiac Surgery involving the use of an operating room. Surgical Cardiovascular Cases shall be measured each year from January 1 to December 31. SMG shall make payments to the Physician in the applicable amount set forth below within 90 days after the end of the applicable year.	
Surgical Cardiovascular Cases	Incentive Compensation
600	\$400,000
601	\$401,000
602	\$402,000

Exhibit 4 (emphasis added).

79. SMG, acting through Dr. Shetty, and Dr. Agnihotri executed a Third Amendment, effective January 1, 2019, that (1) increased the amount of incentive compensation Dr. Agnihotri would receive for hitting the threshold from \$400,000 to \$500,000 and (2) reduced the ceiling for

¹⁴ Around the time of the Second Amendment, Steward made Dr. Agnihotri the System Chief of Cardiac Surgery for Steward. Dr. Agnihotri continued to perform his surgeries at SEMC.

the incentive compensation from \$800,000 to \$700,000. The agreement left unchanged the formula of \$1,000 per case above the threshold and up to the ceiling.

80. At the same time, SMG added a separate provision to Dr. Agnihotri's agreement for a "Quality Incentive Compensation," under which Dr. Agnihotri was eligible to receive up to \$100,000 per year.

81. Below is a portion of the incentive compensation provision from the Third Amendment to Dr. Agnihotri's employment agreement. The Third Amendment is attached as Exhibit 5.

EXHIBIT B	
Commencing on January 1, 2019, Physician shall be eligible to receive Incentive Compensation of up to \$700,000 per year during the term of this Agreement. Physician shall receive as Incentive Compensation the amount listed below which corresponds to the number of surgical cardiovascular cases performed by the St. Elizabeth's Medical Center Division of Cardiac Surgery during each year during the term of this Agreement. For purposes of calculating Incentive Compensation, a "Surgical Cardiovascular Case" shall mean any surgical cardiac procedure performed by the Division of Cardiac Surgery involving the use of an operating room. Surgical Cardiovascular Cases shall be measured each year from January 1 to December 31. SMG shall make payments to the Physician in the applicable amount set forth below within ninety (90) days after the end of the applicable year.	
Surgical Cardiovascular Cases	Incentive Compensation
600	\$ 500,000.00
601	\$ 501,000.00
602	\$ 502,000.00

Exhibit 5 (emphasis added).

82. The defendants did not perform a fair market value analysis of the compensation arrangement or any of its amendments, prior to or at the time of execution of the employment agreements.

83. In June 2022, SMG and Dr. Agnihotri entered into the Fourth and Fifth Amendments to his employment agreement, which terminated the Incentive Compensation provision of his agreement, backdated to an effective date of April 1, 2022. At or around that same time, Dr. Agnihotri lost his position as the System Chief of Cardiac Surgery for Steward. The Fourth Amendment is attached as Exhibit 6, and the Fifth Amendment is attached as Exhibit 7.

II. SEMC HAD AN INDIRECT COMPENSATION ARRANGMENT WITH DR. AGNIHOTRI, AND SUBMITTED CLAIMS TO MEDICARE IN VIOLATION OF THE STARK LAW

84. Although Dr. Agnihotri was employed by SMG, he had an improper indirect compensation arrangement with SEMC for the entire Relevant Period. All of the requirements set out in 42 C.F.R. § 411.354(c)(2) to establish the existence of an indirect compensation arrangement were met. There was an unbroken chain of financial relationships between SEMC and Dr. Agnihotri, Dr. Agnihotri received aggregate compensation from SMG that varied with, and took into account, the volume or value of his referrals (or other business generated) to SEMC, and SEMC had knowledge that Dr. Agnihotri received aggregate compensation that varied with, or took into account the volume or value of his referrals (or other business generated).¹⁵

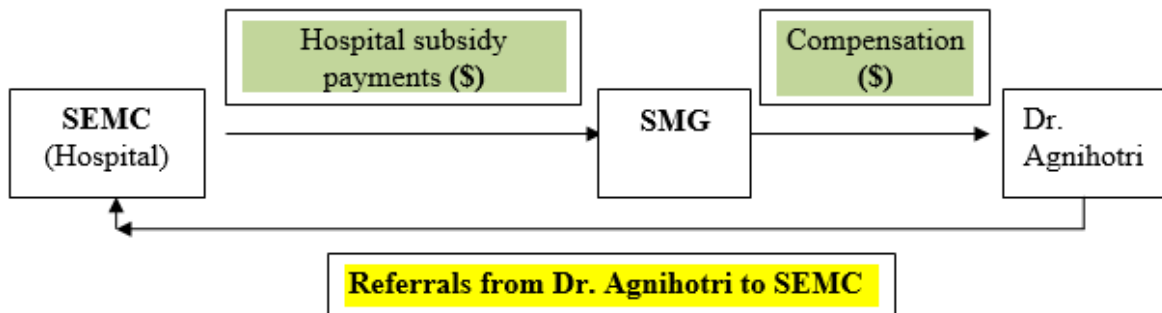
85. The financial links between SEMC and Dr. Agnihotri are shown by the nature of Steward's integrated health care system, to which both SEMC and SMG belonged, the structure

¹⁵ Dr. Agnihotri also had an indirect compensation arrangement with SEMC under the revised regulations effective January 2021, because the individual unit of compensation that Dr. Agnihotri received was not fair market value for services he provided, and the individual unit increased or decreased based on the number of referrals that Dr. Agnihotri made to SEMC.

of Dr. Agnihotri's compensation from SMG, SEMC's knowledge of Dr. Agnihotri's compensation from SMG, and the hospital subsidies that SEMC provided to SMG to assist with Dr. Agnihotri's compensation.

86. SEMC made subsidy payments to SMG to offset SMG's expenses associated with employing Dr. Agnihotri. The defendants reduced these payments by the revenue that SMG expected Dr. Agnihotri to generate for SMG. Steward, which owned both SEMC and SMG, facilitated SEMC's subsidy to SMG by transferring money, through intercompany transfers, between its one subsidiary, SEMC, to its other subsidiary, SMG. SMG in turn paid Dr. Agnihotri.

87. This diagram illustrates the flow of money from SEMC to SMG to Dr. Agnihotri. The transfer of money from SEMC to SMG was facilitated by Steward. The diagram also illustrates Dr. Agnihotri's referrals to SEMC.



88. During the Relevant Period, SEMC, via Steward's intercompany transfers, paid SMG significant hospital subsidies for SMG to compensate Dr. Agnihotri.

89. For example, in 2016 SEMC, via Steward's intercompany transfer, paid SMG a "hospital subsidy" of approximately \$954,300 for Dr. Agnihotri's compensation, and in 2018

SEMC paid SMG a “hospital subsidy” of approximately \$885,437 for Dr. Agnihotri’s compensation.

90. From 2013 through 2021, SEMC paid SMG approximately \$7,454,442 in hospital subsidies for SMG to compensate Dr. Agnihotri.

91. During the Relevant Period, the defendants calculated Dr. Agnihotri’s incentive compensation based, in part, on the number of Surgical Cardiovascular Cases he referred to SEMC. In doing so, the defendants determined Dr. Agnihotri’s compensation in a manner that varied with, and took into account, the volume or value of his referrals to SEMC.

92. During the Relevant Period, Dr. Agnihotri referred patients to SEMC for inpatient and outpatient hospital services. Dr. Agnihotri’s referrals to SEMC violated the Stark Law because his indirect compensation arrangement with SEMC did not satisfy the requirements of any applicable exception to the Stark Law. As discussed in more detail in the next sections, the arrangement did not satisfy any regulatory exception for two independent reasons: (1) Dr. Agnihotri’s aggregate compensation exceeded fair market value, and (2) SMG determined Dr. Agnihotri’s incentive compensation in a manner that took into account the volume or value of his referrals to SEMC or the other business he generated for SEMC. Either one of these reasons removes the arrangement from the protection of the Stark Law’s exception for indirect compensation arrangements.

III. SEMC'S INDIRECT COMPENSATION ARRANGEMENT WITH DR. AGNIHOTRI DID NOT MEET ANY EXCEPTION TO THE STARK LAW

A. The Defendants' Compensation to Dr. Agnihotri Exceeded Fair Market Value

93. As discussed above, an indirect compensation arrangement can comply with the Stark Law, but to do so, among other things, the aggregate compensation must be fair market value.

94. Dr. Agnihotri's compensation did not comply with the Stark Law, however, because SMG paid Dr. Agnihotri aggregate compensation in excess of fair market value, each year from 2013 through 2022. *See* 42 C.F.R. § 411.357(p).

95. SMG paid Dr. Agnihotri a \$1 million dollar sign-on bonus. The sign-on bonus is part of Dr. Agnihotri's aggregate compensation, and contributed, in certain years, to his aggregate compensation exceeding fair market value.

96. The defendants determined Dr. Agnihotri's incentive compensation in a manner that took into account (i) the total number of Surgical Cardiovascular Cases he referred to SEMC in which he personally performed the procedure, and (ii) the Surgical Cardiovascular Cases referred to SEMC by other physicians in the Division that the other physicians performed. Thus, Dr. Agnihotri's aggregate compensation included compensation for services that he did not personally perform, and therefore could not possibly be fair market value.

97. The Medical Group Management Association ("MGMA"), an independent medical industry organization, provides benchmarking for physician compensation based on physician specialty and locality. Hospitals frequently use MGMA benchmarking when assessing fair market value.

98. The defendants' internal guidance during the Relevant Period stated that "SMG uses MGMA for FMV determinations" and that "[w]hen compensation exceeds the 75th %tile of MGMA Benchmark, a written explanation is required."

99. For most, if not all, of the years in the Relevant Period, SMG's aggregate compensation to Dr. Agnihotri exceeded the ninetieth percentile for cardiovascular surgeons based in the eastern region of the United States based on the MGMA benchmarking. In contravention of their own internal guidance, the defendants did not document a written explanation justifying Dr. Agnihotri receiving compensation in excess of the seventy-fifth percentile of MGMA benchmarking.

100. For example, in 2014, Dr. Agnihotri's aggregate compensation was \$1,570,001, and far exceeded the MGMA 90th percentile of physician compensation for cardiovascular surgeons in the eastern United States, which was \$821,360. Even if one removes Dr. Agnihotri's salary for administrative services and adjusts for 80 percent clinical time¹⁶—then his aggregate compensation was \$1,326,847, which exceeded the MGMA 90th percentile of physician compensation for cardiovascular surgeons working 0.8 full time equivalent hours, which was \$621,094.

101. In 2016, Dr. Agnihotri's aggregate compensation was \$1,570,000, and far exceeded the MGMA 90th percentile of physician compensation for cardiovascular surgeons in the eastern United States, which was \$989,911. If one removes Dr. Agnihotri's salary for

¹⁶ During the Relevant Period, Dr. Agnihotri's base compensation required him to spend eighty percent of his time on clinical services and twenty percent, or at least eight hours per week, on administrative duties.

administrative services and adjusts for 80 percent clinical time, then his aggregate compensation was \$1,420,000, which exceeded the MGMA 90th percentile of physician compensation for cardiovascular surgeons working 0.8 full time equivalent hours, which was approximately \$791,929.

102. In 2017, Dr. Agnihotri's aggregate compensation was \$1,466,001, and far exceeded the MGMA 90th percentile of physician compensation for cardiovascular surgeons in the eastern United States, which was \$961,350. If one removes the portion of Dr. Agnihotri's salary for administrative services and adjusts for 80 percent clinical time—then his aggregate compensation was \$1,316,001, which exceeded the MGMA 90th percentile of physician compensation for cardiovascular surgeons working 0.8 full equivalent time hours, which was approximately \$769,080.

103. Because SMG's aggregate compensation to Dr. Agnihotri exceeded fair market value during the Relevant Period, the indirect compensation arrangement between SEMC and Dr. Agnihotri did not satisfy the fair market value requirements of the Stark Law's exception for indirect compensation arrangements.

B. The Defendants Determined Dr. Agnihotri's Incentive Compensation in a Manner that Took Into Account the Volume or Value of His Referrals to SEMC and the Other Business He Generated for SEMC

104. As discussed above, an indirect compensation arrangement can comply with the Stark Law if, among other things, the compensation is *not* determined in a manner that takes into account the volume or value of referrals. As described below, however, during the Relevant Period, Dr. Agnihotri's compensation was determined in a manner that took into account the volume or value of his referrals to SEMC and the other business he generated for SEMC.

105. During the Relevant Period, Dr. Agnihotri was eligible for incentive compensation which varied based on the volume of his Surgical Cardiovascular Cases and, thus, was determined in a manner that took into account the volume or value of his referrals and the other business he generated for SEMC. Dr. Agnihotri's incentive compensation calculation took into account Dr. Agnihotri's referrals of Medicare patients to SEMC for cardiac surgeries, and his referrals of patients with other federal insurance or private insurance to SEMC for cardiac surgeries. The latter constitutes the other business generated by Dr. Agnihotri for SEMC.

106. SMG Paid Dr. Agnihotri approximately \$4,868,500 in incentive compensation based on cases performed by the Division of Cardiac Surgery at SEMC from 2013 through 2021, including cases that Dr. Agnihotri referred to SEMC.

107. Dr. Agnihotri would not have received any incentive compensation for the cases referred and performed by the Division in 2013, 2014, and 2015, if his referrals to SEMC for the cases in which he personally performed the procedure were not included in the calculation because the inclusion of his referrals were necessary to meet the threshold.

108. The following is a chart demonstrating the incentive compensation threshold for each year and the actual number of Surgical Cardiovascular Cases performed by Dr. Agnihotri compared to the other physicians in the Division.¹⁷

¹⁷ Based upon information and belief, for each year that the Division hit the threshold, SMG included cases Dr. Agnihotri referred and performed at SEMC in the Division's total cases. The United States has data on the breakdown of the Surgical Cardiovascular Cases by the Division's individual physicians through August 2018. The United States intends to seek data for the remainder of the Relevant Period during discovery in this case.

Year of Cases ¹⁸	Threshold	Cases Dr. Agnihotri Referred to and Performed at SEMC	Cases performed at SEMC by Others in Division	Total Cases	Dr. Agnihotri's Incentive Comp Based on the Cases
2013	400	257	275	532	\$498,000
2014	400	298	239	537	\$505,500
2015	400	257	363	620	\$620,000
2016	400	274	442	716	\$716,000
2017	400	250	420	670	\$670,000
2018	400	At least 181	At least 305	706	\$706,000
2019	600	---	---	648	\$548,000
2020	600	Less than 600 ¹⁹			\$0
2021	600	---	---	705	\$650,000

109. Once the threshold was met in any given year, SMG paid Dr. Agnihotri a lump sum incentive bonus and an additional amount of money for each Surgical Cardiovascular Case performed by the Division at SEMC above the threshold, up to a ceiling, including cases he referred.

110. For example, in 2013, the number of Surgical Cardiovascular Cases the Division performed met the threshold for Dr. Agnihotri to receive incentive compensation in or around October. In November and December of that year, Dr. Agnihotri referred approximately forty-two Surgical Cardiovascular Cases to SEMC, including approximately twenty-two Surgical

¹⁸ In this chart, the year indicates the year in which the cases were performed; the Incentive Compensation was paid out the following calendar year.

¹⁹ Due to the Covid-19 pandemic, there was a restriction on elective surgeries and the Division performed less than 600 Surgical Cardiovascular Cases.

Cardiovascular Cases for Medicare beneficiaries, and performed the surgeries on the patients he referred to SEMC. He received additional incentive compensation for each of those referrals.

111. As another example, in 2016, the number of Surgical Cardiovascular Cases performed by the Division met the threshold for Dr. Agnihotri to receive incentive compensation in or around July. In August through December of that year, Dr. Agnihotri referred approximately 119 Surgical Cardiovascular Cases to SMEC, including approximately 62 Surgical Cardiovascular Cases for Medicare beneficiaries, and performed the surgeries on the patients he referred to SEMC. He received additional incentive compensation for each of those referrals.

112. Dr. Agnihotri's Incentive Compensation was not calculated based on his professional services, personal productivity, or work relative value units ("wRVUs").²⁰

113. The defendants interpreted Surgical Cardiovascular Cases for purposes of calculating Dr. Agnihotri's incentive compensation very broadly and did not take into account the difficulty or the length of time of the cases, only the mere fact that the cases occurred. SEMC could bill for each of the Surgical Cardiovascular Cases that Dr. Agnihotri referred to SEMC and performed using SEMC's operating rooms.

114. The defendants' structured Dr. Agnihotri's Incentive Compensation in a manner that did not reward him for his professional services in performing surgeries, but in a manner that

²⁰ wRVUs represent the relative amount of physician work, resources, and expertise necessary to provide a service to a patient and serve as a productivity metric for work performed by physicians. It is not unusual in the hospital industry to determine productivity bonuses for physicians based on the physician's personally performed wRVUs. In that scenario, the wRVU metric does not take into account the volume or value of referrals.

rewarded him for making referrals to SEMC. The structure of the incentive compensation aligned the defendants' desire to increase cardiac cases at SEMC and to increase SEMC's revenue with Dr. Agnihotri's personal financial interest.

115. When asked why Steward intentionally used a broad definition of a case, Dr. Callum testified²¹ that Steward wanted the language to be clear: "Either you brought a patient into the operating room or you didn't, and that's how we're going to count the cases."

116. The defendants used SEMC's data on the number of cases performed at SEMC to calculate Dr. Agnihotri's incentive compensation. Dr. Callum was aware that this is how the incentive compensation was calculated in practice because Dr. Agnihotri made it a habit to email Dr. Callum at the beginning of each year to request his incentive compensation and confirm the amount, while attaching data obtained from SEMC. Below are emails that Dr. Agnihotri sent to Dr. Callum in 2014 and 2015 concerning his incentive compensation based on the Division's cases in 2013 and 2014. In both instances, Dr. Agnihotri attached data obtained from SEMC's records. The emails and their attachments are attached as Exhibits 8 and 9.

²¹ Dr. Callum testified pursuant to a Civil Investigative Demand.

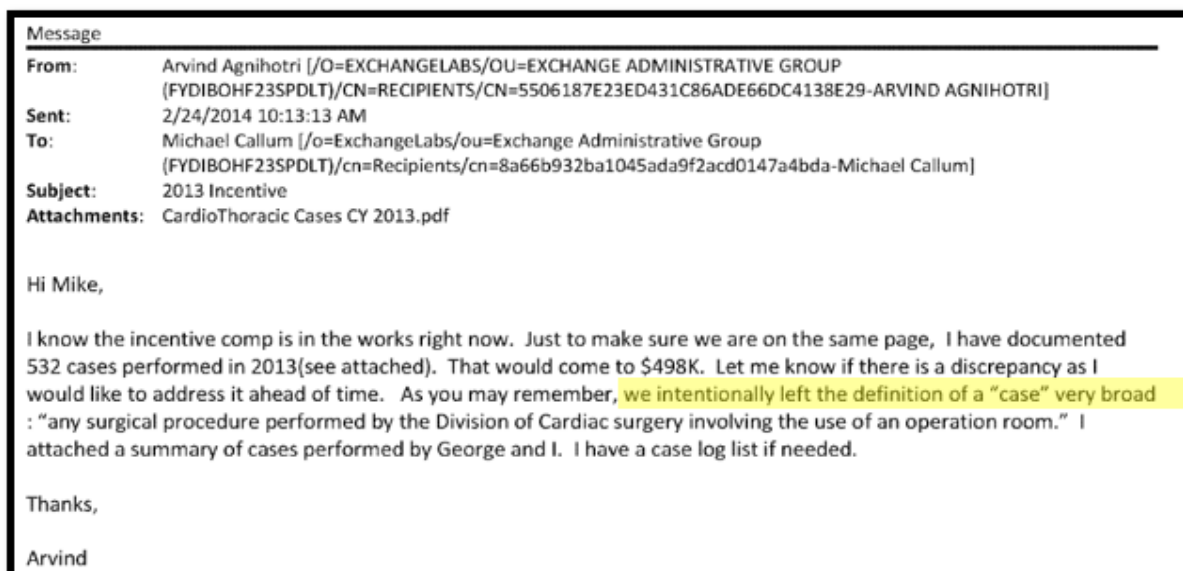


Exhibit 8 (emphasis added).

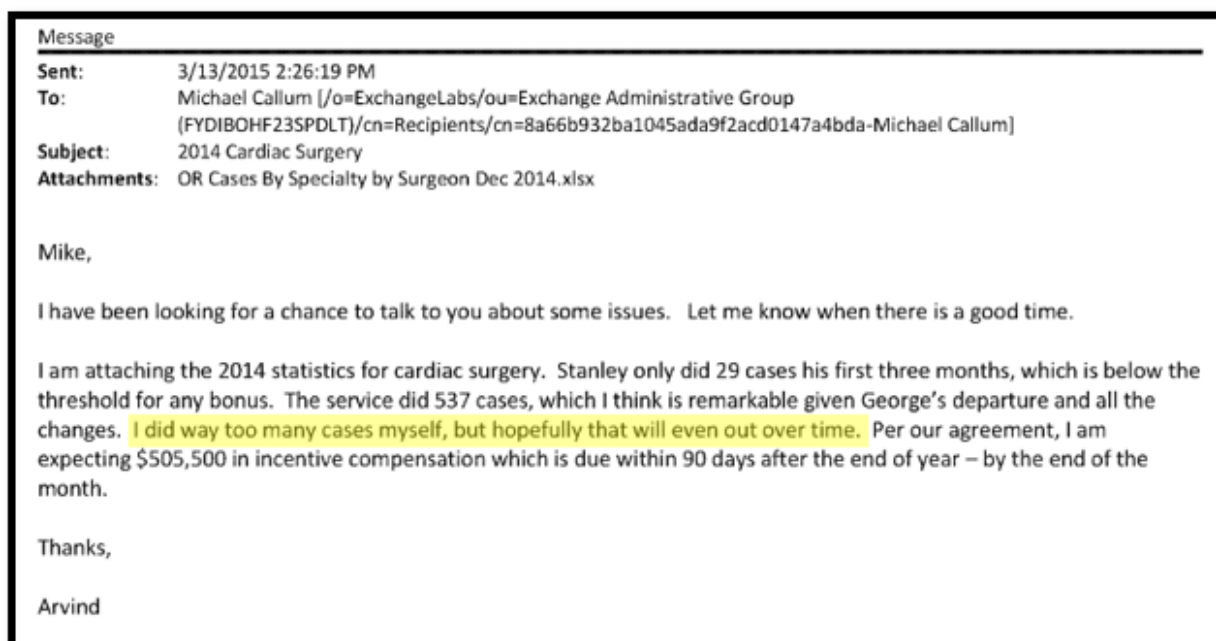


Exhibit 9 (emphasis added).

In both of these examples, Dr. Callum did not respond to Dr. Agnihotri in writing. In both instances, SMG paid Dr. Agnihotri's incentive compensation consistent with Dr. Agnihotri's

calculations using the SEMC data. In the first email Dr. Agnihotri reminded Dr. Callum “we intentionally left the definition of ‘case’ very broad.” Exhibit 8. In the second email, Dr. Agnihotri stated, “I did way too many cases myself, but hopefully that will even out over time.” Exhibit 9.

117. When on behalf of SMG, Dr. Callum entered into the employment agreement with Dr. Agnihotri, he knew that Dr. Agnihotri’s incentive compensation was volume-based. Dr. Callum testified that he understood that a purpose of the volume-based incentive compensation was to compensate Dr. Agnihotri for his success in growing the Division—i.e., more cases, including Dr. Agnihotri’s own—at SEMC.

118. Dr. Callum also testified that the reason SMG required that the Division hit a threshold number of cases before Dr. Agnihotri would be eligible for incentive compensation was that Steward wanted to double the cases performed at SEMC before Dr. Agnihotri received any additional compensation.

119. Dr. Callum further testified that a goal of the incentive compensation structure was to incentivize Dr. Agnihotri to increase the number of cardiovascular cases at SEMC. Within two years of Dr. Agnihotri starting at SEMC, the Division “more than doubled the surgical volume of cardiac surgery.”

120. Because SMG paid Dr. Agnihotri incentive compensation that it determined in a manner that took into account the volume or value of his referrals to SEMC, or other business he generated for SEMC, the indirect compensation arrangement between SEMC and Dr. Agnihotri did not satisfy the requirements of the Stark Law’s exception for indirect compensation arrangements.

IV. THE DEFENDANTS KNEW THAT THEY SUBMITTED, OR CAUSED THE SUBMISSION, OF FALSE CLAIMS, STATEMENTS, AND RECORDS TO MEDICARE, BY BILLING FOR DESIGNATED HEALTH SERVICES THAT DR. AGNIHOTRI REFERRED TO SEMC IN VIOLATION OF THE STARK LAW

121. At all relevant times, as already set forth above, the defendants acted knowingly—that is, with actual knowledge, in deliberate ignorance, or with reckless disregard—with respect to the fact that they were submitting or causing the submission of false claims to Medicare as alleged herein and that they were making or causing to be made false records or statements material to false claims or to get claims paid.

A. The Defendants Knew that They were Required to Comply with the Stark Law

122. At all times relevant to this lawsuit, the Medicare statutory and regulatory rules described above, see above ¶¶ 37–56, applied to SEMC as an enrolled Medicare provider.

123. During the Relevant Period, NGS was the Medicare Part A intermediary and Part B carrier to which SEMC and SMG submitted Medicare enrollment forms, claims, and cost reports.

124. Throughout the Relevant Period, SEMC and SMG submitted Medicare enrollment and reenrollment applications. Examples of the applications are listed in Exhibit 10, which sets forth the specific Steward entity that submitted the application as well as the date of submission and the certification signatory. On those applications, SEMC and SMG certified that they understood that Medicare conditioned payment on compliance with the Stark Law.

125. In its Medicare enrollment applications, SEMC certified, among other things:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. **I understand that payment of a claim by**

Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law), and on the provider's compliance with all applicable conditions of participation in Medicare.

See, e.g., Exhibit 1 (emphasis added).

126. SMG similarly certified its understanding of the Stark Law in its enrollment applications. *See* Medicare Enrollment Application, CMS, <https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms855b.pdf> (last visited Dec. 6, 2023) (“I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law)[.]”).

127. SEMC and SMG repeatedly certified to Medicare that they understood that Medicare's payment of a claim is conditioned upon compliance with the Stark Law. *See* Exhibit 10 and an example at Exhibit 1.

128. SEMC similarly certified on its annual cost reports its familiarity with the laws and regulations “regarding the provision of health care services,” which includes the Stark Law. *See* Exhibit 11 which identifies examples of SEMC's cost reports during the Relevant Period.

129. A Steward presentation entitled “Steward Physician Contracting Compliance Overview, Process and Policies,” dated April 1, 2015, provides an overview of the Stark Law, AKS, and the FCA. The presentation is Exhibit 12. The training sets out the SMG Employment agreement workflow. The first steps are to complete the Business Plan Request and the Business Judgment Factors. None of the defendants completed these steps for Dr. Agnihotri's

Employment Agreement or amendments. The training expressly states that incentive compensation should be included in the total compensation used to calculate fair market value. None of the defendants contemporaneously analyzed the fair market value of the incentive compensation offered and paid to Dr. Agnihotri. Their failure to do so evidences their actual knowledge of their noncompliance with the Stark Law, or their reckless disregard, or deliberate ignorance.

Fair Market Value (FMV) Justification

- MGMA /Sullivan Cotter Survey Comparison
- Other “Business Judgment” qualities to support FMV if over 75%tile (see examples on next page)
- Clinical and Administrative dollars must be valued separately
- Should take billing into consideration when determining if rate is FMV if physician will do the professional billing
- Compensation terms that are not standard to all physicians should be added into total compensation to calculate FMV, including:
 - CME/ Professional Expense reimbursement
 - Malpractice insurance
- Additional compensation should be added into total compensation to calculate FMV, including:
 - Signing Bonus
 - Incentive Compensation
 - Moving Allowance
 - Loan Repayment

Exhibit 12.

130. The presentation highlights and references the *Halifax*, *Tuomey*, and *Intermountain Health Care* cases, each of which involved a hospital violating the Stark Law by taking into account the volume or value of referrals in determining physicians’ compensation. Steward highlighted those matters, on the slide shown below, with bullet points regarding the award of damages in *Tuomey*, and the settlement agreements in *Halifax* and *Intermountain*

Health Care. Steward's presentation specifically notes that each matter involved allegations that payments from the hospitals took into account the volume or value of the physicians' referrals.

November 13, 2013...\$85M

Halifax Hospital Medical Center settles with DOJ after being accused of entering into financial relationships with medical oncologists and neurosurgeons in violation of Stark and FCA (incentive bonuses took into account the volume or value of the physician's referrals to the hospital because fees for DHS were included in the bonus pool)

October 1, 2013...\$238M

Award of damages after a jury trial against Tuomey Healthcare System regarding allegations that physician employment agreements violated the Stark law (in excess of FMV and based on the volume of business generated)

April 3, 2013....\$25.5M

Intermountain Health Care settles with DOJ following self-disclosure of unlawful financial relationships with physicians (payment took into account volume/value of referrals, unwritten leases, unwritten physician service agreements)

Exhibit 12.

131. A presentation from Steward's Office of Corporate Compliance & Privacy Training, dated November 2014, addresses the Stark Law and provides examples of potential Stark Law violations including one strikingly similar to Dr. Agnihotri's compensation arrangement: "A hospital compensates a physician group under contracts in excess of fair market value and took into account the volume of referrals from the physicians to the hospital in calculating compensation." The presentation is Exhibit 13.

132. After the dates of both of these presentations, SMG amended Dr. Agnihotri's contract twice during the Relevant Period (the Second and Third Amendments), without conducting a fair market value determination and keeping the structure of Dr. Agnihotri's

incentive compensation, which was determined in a manner that took into account the volume of his referrals to SEMC or the other business he generated for SEMC.

B. The Defendants Did Not Follow Their Own Policies When Entering Into The Compensation Arrangements with Dr. Agnihotri


133. During the Relevant Period, Steward, SMG, and SEMC had policies and procedures in place to ensure compliance with the Stark Law, but they did not follow those policies and procedures with respect to Dr. Agnihotri's employment agreement.

134. At all relevant times, as evidenced by their own policies, the defendants knew the requirements of the exceptions under the Stark Law—specifically that any compensation to a physician must be fair market value, commercially reasonable, and not be determined in a manner that takes into account the volume or value of referrals.

135. To ensure compliance with the Stark Law, the defendants put in place policies and practices, and issued guidance to employees, concerning physician compensation arrangements.

136. For example, Steward's internal guidance during the Relevant Period clearly set forth its understanding of the fair market value requirement. The following is from a Steward and SMG presentation:

Fair Market Value



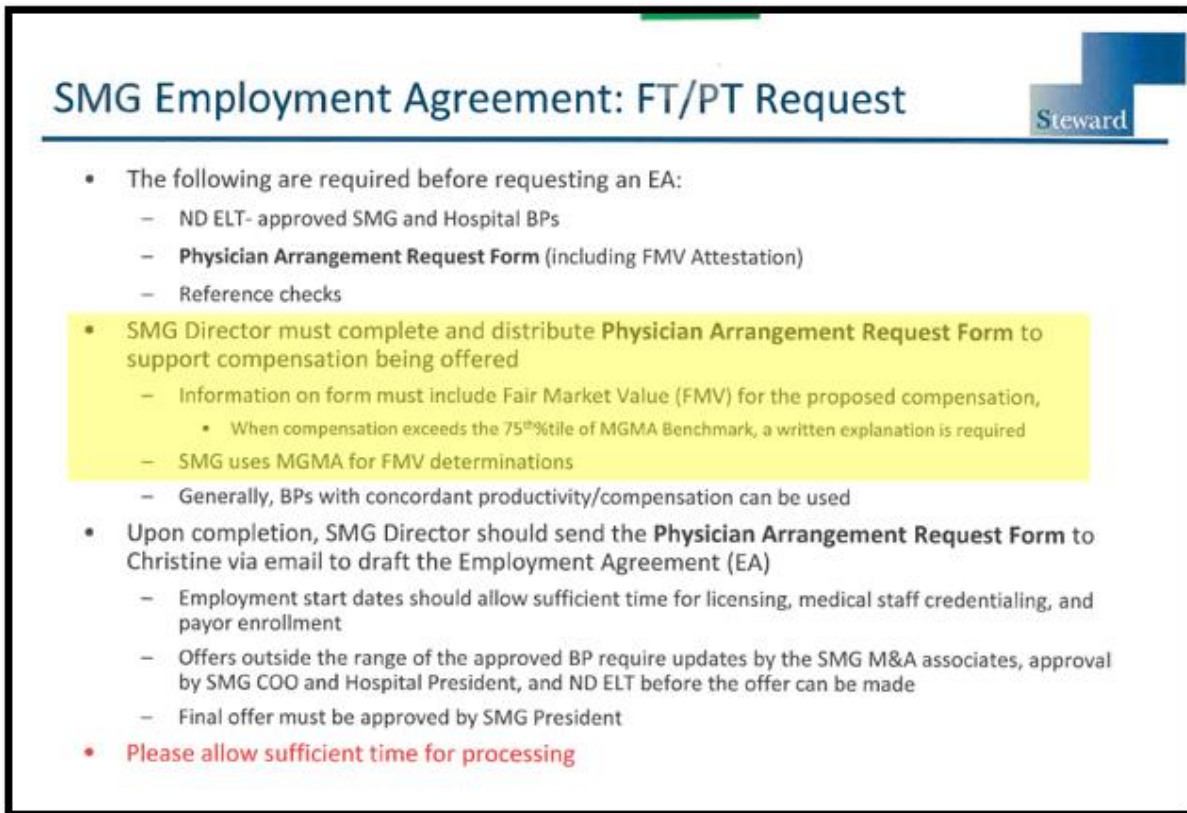
- All financial arrangements with physicians or physician groups must meet fair market value and commercial reasonableness even in the absence of referrals between the parties
- Fair market value is consistent with the general value resulting from a bona fide arm's length transaction between well informed parties otherwise not in a position to generate business for the other party
- Fair market value does not take into account the value or volume of referrals between the parties

Exhibit 14. The full slide deck is attached as Exhibit 14.

137. A Steward policy required “the SMG President and the SMG Chief Operating Officer to approve the business plan for each employment agreement, and amendments, [] including documentation of fair market value.” Steward policy further required that “Any Provider Arrangement submitted for approval must be accompanied by a complete written analysis of the business judgment factors and documentation of fair market value supporting the provider agreement.”

138. SEMC’s CFO was aware of these policies concerning compliance with the Stark Law. For example, during his time as the CFO for SEMC—approximately May 2016 to November 2017—Mr. Nocie reviewed a Steward slide deck entitled “Physician Services Resource Document [:] Recruitment, Contracting and Provider Enrollment Processes.” An SMG Financial Business Analyst directed Mr. Nocie to the slide deck. The title page included the logos for Steward and SMG. *See* Exhibit 14. The document lays out the approval process for physician employment agreements discussed above. Below is a copy of the page from that

presentation on which Steward laid out the steps needed for SMG to enter into an Employment Agreement (“EA”) with a physician.



SMG Employment Agreement: FT/PT Request

Steward

- The following are required before requesting an EA:
 - ND ELT- approved SMG and Hospital BPs
 - **Physician Arrangement Request Form** (including FMV Attestation)
 - Reference checks
- SMG Director must complete and distribute **Physician Arrangement Request Form** to support compensation being offered
 - Information on form must include Fair Market Value (FMV) for the proposed compensation,
 - When compensation exceeds the 75thtile of MGMA Benchmark, a written explanation is required
 - SMG uses MGMA for FMV determinations
 - Generally, BPs with concordant productivity/compensation can be used
- Upon completion, SMG Director should send the **Physician Arrangement Request Form** to Christine via email to draft the Employment Agreement (EA)
 - Employment start dates should allow sufficient time for licensing, medical staff credentialing, and payor enrollment
 - Offers outside the range of the approved BP require updates by the SMG M&A associates, approval by SMG COO and Hospital President, and ND ELT before the offer can be made
 - Final offer must be approved by SMG President
- **Please allow sufficient time for processing**

Exhibit 14 (emphasis added).

137. SMG did not follow these steps, or Steward’s policies, with respect to Dr. Agnihotri’s employment agreement or any of its subsequent amendments. Nor did Steward ensure that SMG followed Steward’s policies. SMG did not complete and distribute a Physician Arrangement Request Form (“PARF”). The SMG President and the SMG Chief Operating Officer did not approve a business plan, including documentation of fair market value, for Dr. Agnihotri’s employment agreement and amendments. Neither Dr. Callum, who negotiated Dr.

Agnihotri's employment agreement, nor anyone else from SMG ever submitted for approval a complete written analysis of the business judgment factors and documentation of fair market value supporting Dr. Agnihotri's employment agreement and amendments.

138. Despite Dr. Agnihotri's aggregate compensation being in excess of the "75thtile of MGMA benchmark" the defendants did not contemporaneously document a written justification for that decision.

139. The defendants' internal policies required completion of a PARF to document the requisite written analysis for physician employment agreements and compensation. The defendants did not complete a PARF for Dr. Agnihotri's original employment agreement, nor did they do so for the first, second, or third amendments.

140. The defendants did create a draft PARF for the Second Amendment to Dr. Agnihotri's employment agreement, but it was not finalized. They did not include the final base compensation for the Second Amendment and did not analyze the incentive compensation portion of Dr. Agnihotri's compensation or his wRVUs in their draft PARF. In the draft PARF, the defendants did not evaluate whether Dr. Agnihotri's aggregate compensation, including his base salary for clinical services and administrative duties plus incentive compensation, would be fair market value. The defendants did not analyze whether the incremental amount that Dr. Agnihotri would receive for each additional case the Division performed above the threshold for the incentive compensation was fair market value. The defendants never finalized the draft PARF, and never finalized a PARF providing a written analysis of the compensation terms included in the Second Amendment to Dr. Agnihotri's employment agreement.

141. The defendants had policies and procedures relating to whether a compensation agreement with a physician would be proper under the Stark Law. SMG did not, however, follow the policies and procedures with respect to Dr. Agnihotri's compensation arrangements. The defendants had either actual knowledge, deliberately ignored, or recklessly disregarded that Dr. Agnihotri's compensation arrangements did not comply with the Stark Law's exceptions because they did not follow their own policies designed to check for compliance.

C. Dr. Callum and Dr. Shetty, who Executed, on Behalf of SMG, the Compensation Arrangements with Dr. Agnihotri, Were Trained on the Stark Law and Knew, Recklessly Disregarded, or Deliberately Ignored that Dr. Agnihotri's Compensation Agreement was Improper

142. All Steward employees are bound by Steward's Code of Conduct and must complete annual compliance training and testing covering topics, including the Stark Law, as a condition of their continued employment. The Code of Conduct states that Steward workforce members will "never offer or give anything of value to anyone . . . in an attempt to obtain patient business." <https://content.steward.org/sites/default/files/Code%20of%20Conduct-WEB-MAR17.pdf> (last visited Dec. 15, 2023). Dr. Callum and Dr. Shetty, the signatories to Dr. Agnihotri's employment agreement and amendments, were bound by Steward's Code of Conduct and completed training on the Stark Law.

143. Dr. Callum testified that he personally completed annual training from Steward that covered the Stark law. Dr. Callum testified that he believed "Stark is in place to prevent the taking into account the volume or value of referrals from referring physicians."

144. In July 2013, Dr. Shetty received a copy of Steward's compliance policy entitled "Gifts & Business Courtesies to Physicians from Steward Entities." *See* Exhibit 15. The policy

provides an overview of the Stark Law and specifies that violations of the Stark Law may also lead to liability under the FCA.

145. Dr. Callum signed Dr. Agnihotri's original employment agreement and the First Amendment, on behalf of SMG. He did so *after* having been trained on the Stark Law and *despite* knowing that Dr. Agnihotri's compensation varied based on the volume of cases performed at SEMC and, thus, was determined in a manner that took into account the volume of his referrals to SEMC or the other business he generated for SEMC.

146. Dr. Shetty signed the Third and Fourth Amendments, on behalf of SMG, *after* he received Steward's compliance policy addressing the Stark Law and *despite* knowing that Dr. Agnihotri's compensation varied based on the volume of cases performed at the hospital and, thus, was determined in a manner that took into account the volume of his referrals to SEMC or the other business he generated for SEMC.

147. Dr. Callum and Dr. Shetty were both agents of SMG, and were in SMG's control group as successive SMG Presidents, when they signed Dr. Agnihotri's compensation arrangements. They knew the provisions of the agreements they signed. They knew the requirements of the Stark Law and Steward's policies on physician compensation arrangements. As such, SMG knew, within the meaning of the FCA, that Dr. Agnihotri's compensation arrangements violated the Stark Law.

D. Defendants' Employees Internally Voiced Concerns to Defendants' Leadership that Dr. Agnihotri's Compensation Arrangement was Improper, but the Defendants Ignored Their Concerns

148. Steward and SEMC knew that SMG paid Dr. Agnihotri incentive compensation that it determined in a manner that took into account the volume of value of Dr. Agnihotri's

referrals to SEMC and the other business he generated for SEMC. During the Relevant Period, SEMC's President and Chief Executive Officer ("CEO"), CFO, and Chief Operating Officer ("COO"), were all aware that SMG paid Dr. Agnihotri in a manner that took into account the volume or value of Dr. Agnihotri's referrals to SEMC or the other business he generated for SEMC.

149. Beth Hughes was the President and CEO of SEMC from approximately December 2015 to December 2016. Ms. Hughes was employed by Steward, and an executive at SEMC. Ms. Hughes testified that during her time at SEMC, she raised concerns about Dr. Agnihotri's incentive compensation with Dr. Callum on multiple occasions, both in private and in a meeting with others. Ms. Hughes also discussed her concerns with her senior leadership team at SEMC, including Joseph Nocie and Tim Daugherty, and with Laura Tortorella, a senior leader at Steward.²²

150. Ms. Hughes testified that she referred to Dr. Agnihotri's incentive compensation arrangement as a "per click" arrangement, because he got paid more money for each surgery. She was concerned because the arrangement was not based on Dr. Agnihotri's wRVUs, but instead was a set amount per surgery.

151. In 2016 Ms. Hughes raised concerns about Dr. Agnihotri's contract in a meeting with others present. Dr. Callum got angry with Ms. Hughes and yelled at her during the meeting. Ms. Hughes testified that another Steward executive, John Polanowicz, told her after the meeting

²² During the time that Ms. Hughes was at SEMC, Ms. Tortorella worked for Dr. de la Torre at Steward either as his Chief of Staff or Steward's Assistant Chief Operating Officer.

to apologize to Dr. Callum. Steward amended Dr. Agnihotri's employment agreement two more times, retaining the prohibited incentive compensation arrangement, after this incident.

152. The relator, Joseph Nocie, was the CFO at SEMC from approximately May 2016 to November 2017. Mr. Nocie was employed by Steward, and an executive at SEMC. During his time as SEMC's CFO, Mr. Nocie knew that Dr. Agnihotri's incentive compensation was determined in a manner that took into account the volume of value of Dr. Agnihotri's referrals to SEMC or the other business he generated for SEMC. Mr. Nocie and Ms. Hughes had discussions with each other about SEMC potentially violating the Stark law. Mr. Nocie raised his concerns about physician compensation, including Dr. Agnihotri's compensation, at budget meetings with SMG.

153. Tim Daugherty was the COO at SEMC from approximately March 6, 2016 through March 31, 2017. He reported to Ms. Hughes and to Steward, while working as an executive at SEMC. Mr. Daugherty believed that Dr. Agnihotri was overcompensated, and he knew that Dr. Agnihotri was paid for every "per click" procedure at SEMC.

154. Given that (i) the defendants had policies and procedures related to the Stark Law, but did not follow them; (ii) the President and CEO of SEMC raised concerns about the structure of Dr. Agnihotri's compensation arrangement to Dr. Callum; and (iii) various executives at SEMC knew SMG determined Dr. Agnihotri's incentive compensation in a manner that took into account the volume or value of his referrals to SEMC, the defendants knew—within the meaning of the FCA—that Dr. Agnihotri's referrals to SEMC, and SEMC's billing Medicare for the services from those referrals, violated the Stark Law.

V. THE DEFENDANTS' FALSE CLAIMS AND STATEMENTS

155. For purposes of the Stark Law, SEMC had an indirect compensation arrangement with Dr. Agnihotri. As discussed above, the indirect compensation arrangement did not satisfy the requirements of any applicable exception to the Stark Law's referral and claims submission prohibitions.

156. Dr. Agnihotri was prohibited under the Stark Law from making referrals to SEMC for designated health services because of his indirect compensation arrangement with SEMC. SEMC was prohibited under the Stark Law from submitting claims to Medicare for designated health services arising from Dr. Agnihotri's prohibited referrals.

157. SMG caused SEMC to submit false claims and statements to Medicare by structuring Dr. Agnihotri's compensation arrangement in a way that violated the Stark Law and did not satisfy any of the Stark Law exceptions.

158. Steward as the parent organization of SMG and SEMC, caused SEMC to submit false claims and statements to Medicare because it knew (or recklessly disregarded or deliberately ignored) that Dr. Agnihotri's compensation arrangements violated the Stark Law and did not satisfy any of the Stark Law exceptions.

159. Steward, SMG, and SEMC knowingly, as defined by the FCA, presented or caused the submission of false claims and statements to Medicare resulting from Dr. Agnihotri's prohibited referrals to SEMC.

A. SEMC Submitted False Claims to Medicare

160. SEMC submitted over 1,000 Medicare claims for designated health services that Dr. Agnihotri referred to SEMC in violation of the Stark Law.

161. The United States estimates that Medicare paid tens of millions of dollars to SEMC for those false or fraudulent claims.

162. Exhibit 16 contains specific examples of SEMC's claims to Medicare for designated health services furnished pursuant to Dr. Agnihotri's prohibited referrals, in violation of the Stark Law.

163. To date, SEMC has not refunded any payments that it received from claims it submitted to Medicare for designated health services arising from Dr. Agnihotri's prohibited referrals, in violation of the Stark Law.

B. SEMC's False Statements to Medicare

164. In submitting claims arising from Dr. Agnihotri's prohibited referrals, SEMC made specific representations about the billed services it furnished that were rendered materially misleading by SEMC's knowing failure to disclose the claims' noncompliance with the Stark Law.

165. Throughout the Relevant Period, SEMC submitted annual Medicare cost reports, including the cost reports listed on Exhibit 11, which sets forth specific cost reports that SEMC submitted during the Relevant Period, as well as the date of submission and signatory.

166. In its cost reports, SEMC certified:

[T]o the best of my knowledge and belief, it [the hospital cost report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar

with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

https://www.costreportdata.com/worksheets/Form_S001.pdf (last visited Dec. 15, 2023).

Because SEMC submitted claims to Medicare that were prohibited under the Stark Law, SEMC's certifications on its cost reports during the Relevant Period were false.

167. Below is an example of a false certification by SEMC on one of its cost reports.

<p>PART II - CERTIFICATION MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.</p> <p>CERTIFICATION BY CHIEF FINANCIAL OFFICER OR ADMINISTRATOR OF PROVIDER(S)</p> <p>I HEREBY CERTIFY that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by STEWARD ST. ELIZABETH'S MEDICAL CTR (22-0036) (Provider Name(s) and Number(s)) for the cost reporting period beginning 01/01/2017 and ending 12/31/2017, and to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.</p> <p><input checked="" type="checkbox"/> I have read and agree with the above certification statement. I certify that I intend my electronic signature on this certification statement to be the legally binding equivalent of my original signature.</p> <p style="text-align: right;"> <u>(Signed) VICTORIA LOBBAN</u> <u>Chief Financial Officer or Administrator of Provider(s)</u> <u>SR CHIEF FINANCIAL OFFICER</u> <u>Title</u> <u>05/15/2019 14:41</u> <u>Date</u> </p>
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168. SEMC expressly and falsely certified compliance with the Stark Law in its annual cost reports, which, as explained above, constituted SEMC's final claim for items and services provided to Medicare beneficiaries for that year.

169. The cost reports identified on Exhibit 11 contain false statements by SEMC to Medicare.

VI. MATERIALITY

170. The violations in this Complaint are not minor or insubstantial. They implicate the core concerns of the Stark Law.

171. As already set forth above, the fact that SEMC's Medicare claims at issue were prohibited under the Stark Law was material to Medicare's decision whether to pay those claims.

172. SEMC's false representations in its Medicare enrollment forms and cost reports—certifying prospectively and retrospectively that their claims complied with the Stark Law—were material to Medicare's decision whether to pay SEMC's claims; were intended to induce Medicare to pay those claims; and were material to SEMC's obligation to refund improper reimbursements to the United States.

173. The Stark Law expressly states that hospitals may not bill, and Medicare may not pay, claims for designated health services referred in violation of the statute. *See* 42 U.S.C. §§ 1395nn(a)(1), 1395nn(g)(1).

174. Further, the accompanying regulations require the timely refund of any payments received in violation of the Stark Law. 42 C.F.R. § 411.353(d).

175. As noted above, on its provider enrollment form and elsewhere, CMS identifies compliance with the Stark Law as a condition of payment for Medicare claims.

176. Compliance with the Stark Law goes to the essence of Medicare's bargain with participating healthcare providers. The Stark Law plays a key role in ensuring that services are reasonable and necessary, and not provided merely to enrich the parties in a financial relationship at the expense of federal health programs and their beneficiaries.

177. For these reasons, the United States routinely pursues or settles cases, like this one, alleging that entities and individuals submitted or caused the submission of claims that were false because they violated the Stark Law.

178. For example, in *United States v. Rogan*, 459 F. Supp. 2d 692 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008), the United States obtained a judgment against a hospital executive who knowingly had caused the hospital to submit false claims resulting from referrals by physicians whose compensation arrangements with the hospital did not satisfy the requirements of any applicable exception to the Stark Law, including because the compensation paid exceeded fair market value of the physicians' services.

179. In *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, No. 3:05-cv-02858 (MBS) (D.S.C.), *aff'd*, 792 F.3d 364 (4th Cir. 2015), the United States obtained a judgment against a hospital that had compensation arrangements with physicians that failed to satisfy the requirements of any applicable exception to the Stark Law, including because the physicians' compensation exceeded the fair market value of their actual services.

180. In September of 2015, the United States settled a case, *United States ex rel. Reilly v. North Broward Hospital District, et al.*, No. 10-cv-60590 (S.D. Fla.), involving allegations that a hospital had entered into compensation arrangements with certain physicians that did not satisfy the requirements of any applicable exception to the Stark Law, including because the compensation paid exceeded fair market value.

181. In September of 2015, the United States settled two cases, *United States ex rel. Payne, et al. v. Adventist Health System/Sunbelt, Inc., et al.*, No. 12-cv-856 (W.D.N.C) and *United States ex rel. Dorsey v. Adventist Health System Sunbelt Healthcare Corp., et al.*, No. 13-cv-217 (W.D.N.C), involving allegations that a hospital had entered into compensation arrangements with physicians that did not satisfy the requirements of any applicable exception to

the Stark Law, including because the compensation paid was determined in a manner that took into account the volume or value of the physicians' referrals.

182. In August of 2018, the United States settled four cases, *United States ex rel. David Felten, M.D., Ph.D. v. William Beaumont Hospitals, et al.*, No. 2:10-cv-13440 (E.D. Mich.), *United States ex rel. Karen Carbone v. William Beaumont Hospital*, No. 11-cv-12117 (E.D. Mich.), *United States ex rel. Cathryn Pawlusiak v. Beaumont Health System, et al.*, No. 2:11-cv-12515 (E.D. Mich.), and *United States ex rel. Karen Houghton v. William Beaumont Hospital*, No. 2:11-cv-14312 (E.D. Mich.), involving allegations that a hospital had entered into compensation arrangements with certain physicians that did not satisfy the requirements of any applicable exception to the Stark Law, including because the compensation paid exceeded fair market value.

183. In January of 2020, the United States intervened in a case, *United States ex rel. Fischer v. Cmty. Health Network, Inc., et al.*, No. 1:14-cv-1215 (RLY-DKL) (S.D. Ind.), involving allegations that a hospital had entered into compensation agreements with certain physicians that did not satisfy the requirements of any applicable exception to the Stark Law, including because the compensation paid exceeded fair market value or was determined in a manner that took into account the volume or value of the physicians' referrals.

184. In September of 2020, the United States settled a case, *United States of America ex rel. Louis Longo v. Wheeling Hospital, Inc. et al.*, No. 19-cv-192 (N.D.W. Va.), involving allegations that a hospital had entered into compensation agreements with certain physicians that did not satisfy the requirements of any applicable exception to the Stark Law, including because

the compensation paid exceeded fair market value or was determined in a manner that took into account the volume or value of the physicians' referrals.

185. The violations alleged here are material to Medicare's decision to pay.

VII. CONCLUSION

186. During the Relevant Period, SEMC had an indirect compensation arrangement with Dr. Agnihotri that did not meet any exception to the Stark Law. SEMC directly presented or caused to be presented claims to Medicare for designated health services SEMC furnished pursuant to Dr. Agnihotri's referrals in violation of the Stark Law.

187. Because those referrals violated the Stark law, SEMC submitted, or caused the submission of, materially false claims and materially false statements and records to Medicare. Similarly, SMG and Steward, through their actions in structuring, negotiating, and facilitating the compensation arrangements with Dr. Agnihotri, caused SEMC's submission of materially false claims and materially false statements and records to Medicare.

188. Medicare would not have paid SEMC's claims for designated health services furnished pursuant to Dr. Agnihotri's referrals had Medicare known that SEMC had an indirect compensation arrangement with Dr. Agnihotri that did not meet any exception to the Stark Law.

189. Medicare paid the claims at issue under the mistaken belief that all claims submitted by SEMC complied with the Stark Law, based on SEMC's certifications in its provider agreements and SEMC's certifications on its cost reports.

190. Steward, SEMC, and SMG knowingly caused the submission of these false claims to Medicare in violation of the Stark law. They were well aware of the requirements of the Stark Law, including the requirements that compensation arrangements with physicians be fair market

value, not determined in a manner that takes into account the volume or value of referrals, and that a physician employment arrangement must be commercially reasonable, even if the physician made no referrals to the employer. The defendants disregarded their own policies and procedures when they entered into the compensation arrangements with Dr. Agnihotri and ignored the concerns of their employees.

COUNT I
(Against All Defendants)
False Claims Act, 31 U.S.C. § 3729(a)(1)(A)
Presenting and Causing False Claims to Be Presented for Payment

191. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

192. The defendants presented and caused to be presented materially false and fraudulent claims for payment or approval to the United States, including claims to the Medicare program for reimbursement (specific examples of which are identified in Exhibit 16) of designated health services furnished pursuant to Dr. Agnihotri's referrals in violation of the Stark Law.

193. The defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether they were false.

194. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

COUNT II
(Against All Defendants)
False Claims Act, 31 U.S.C. § 3729(a)(1)(B)
Use of False Statements Material to False Claims

195. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

196. The defendants made, used, and caused to be made or used false records or statements—*i.e.*, the false certifications and representations made and caused to be made by SEMC when submitting the false claims for payments and the false certifications made by SEMC in submitting enrollment agreements and annual cost reports (specific examples of which are identified in Exhibits 10 and 11)—to get false or fraudulent claims paid and approved by the United States, and that were material to the United States’ payment of the false claims at issue in this case.

197. SEMC’s false certifications and representations were made for the purpose of getting false or fraudulent claims paid by the United States, and payment of the false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the defendants’ statements and actions.

198. SEMC’s false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms, that the claims to Medicare for designated health services furnished pursuant to Dr. Agnihotri’s referrals complied with the Stark Law, when in fact those claims violated the Stark Law.

199. The false certifications and representations the defendants made and caused to be made were material to the United States’ payment of false claims.

200. The defendants made or caused such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether they were false.

201. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

COUNT III
(SEMC and SMG)
Unjust Enrichment

202. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

203. This is a claim for the recovery of monies by which SEMC and SMG have been unjustly enriched at the expense of the United States.

204. By directly or indirectly obtaining from the United States, through Medicare, funds to which SEMC was not entitled, SEMC was unjustly enriched, and SEMC transferred those funds, or portions thereof, to SMG, and SEMC and SMG are, therefore, liable to account and pay as restitution such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

205. Thus, the United States is entitled to recoup such monies, in an amount to be determined at trial.

COUNT IV
(SEMC)
Payment by Mistake

206. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

207. This is a claim for the recovery of monies the United States paid directly or indirectly to SEMC pursuant to mistaken understandings of fact.

208. The United States' mistaken understandings of fact were material to its decisions to pay claims the SEMC caused to be submitted to Medicare. The United States paid SEMC, for claims for designated health services referred in violation of the Stark Law by Dr. Agnihotri who had an indirect compensation arrangement with SEMC, without knowledge of material facts, and under the mistaken belief that SEMC, was entitled to receive payment for such claims, which were not eligible for payment.

209. The United States' mistaken belief was material to its decision to pay SEMC for such ineligible claims. Accordingly, SEMC is liable for damages to the United States for the total amount of the payments made in error to SEMC by the United States.

210. Thus, the United States is entitled to recoup such monies, in an amount to be determined at trial.

PRAYER FOR RELIEF

The United States requests that judgment be entered in its favor and against the defendants as follows:

- (a) On Counts I and II (False Claims Act), for treble the United States' damages, together with the maximum civil penalties allowed by law;
- (b) On Count III (Unjust Enrichment), in the amount that the SEMC and SMG were unjustly enriched;
- (c) On Count IV (Payment by Mistake), in the amount that SEMC illegally obtained and retained; and
- (d) For pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, the United States requests a trial by jury.

Date: December 15, 2023

Respectfully submitted,

JOSHUA S. LEVY
Acting United States Attorney

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CERTIFICATE OF SERVICE

I certify that I served a copy of the foregoing document on the following counsel, by e-mail on the below date.

Counsel for the relator

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